

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 00N-1565]

Immunology and Microbiology Devices; Classification of Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Test Systems

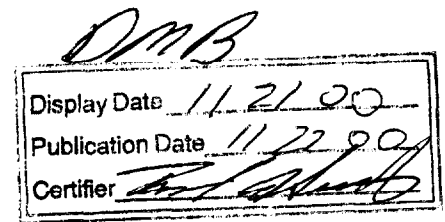
AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Anti-Saccharomyces cerevisiae (*S. cerevisiae*) antibody (ASCA) test system into class II (special controls). The special control that will apply to this device is a guidance document entitled "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications." Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the devices.

DATES: This rule is effective [insert date 30 days after date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Deborah M. Moore, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293.



SUPPLEMENTARY INFORMATION:**I. Background**

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on July 11, 2000, classifying the QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On July 18, 2000, FDA filed a petition submitted

by INOVA Diagnostics, Inc., requesting classification of the QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA into class II under section 513(f)(2) of the act.

After review of the information submitted in the petition, FDA determined that the INOVA Diagnostics QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA can be classified in class II with the establishment of special controls. This device is intended for use in the semi-quantitative in vitro determination of anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibodies (ASCA) in human serum as an aid in the diagnosis of Crohn's disease. FDA believes that class II special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

In addition to the general controls of the act, the INOVA Diagnostics QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA is subject to a special control guidance document entitled "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications."

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of this type of device and, therefore, the device is not exempt from the premarket notification requirements. The test is used in the diagnosis of Crohn's disease and FDA review of data sets and labeling ensure that minimum levels of performance are obtained before marketing and are subject to impartial external quality control before labeling is put into place. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) test system before marketing the device.

On August 16, 2000, FDA issued an order to the petitioner classifying the INOVA Diagnostics QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA, and substantially equivalent devices of this

generic type, into class II under the generic name, anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) test system. FDA identifies this generic type of device as an anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) antibody (ASCA) test system, which is intended to measure *Saccharomyces cerevisiae* (*S. cerevisiae*) antibodies (ASCA) in human serum or plasma as an aid in the diagnosis of Crohn's disease. FDA is codifying this device by adding § 866.5785. This order also identified a special control applicable to this device entitled "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications."

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA knows of only one manufacturer

of this type of device. Classification of these devices in class II will relieve this manufacturer of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e) and may permit small potential competitors to enter the market place by lowering their costs. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, or on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

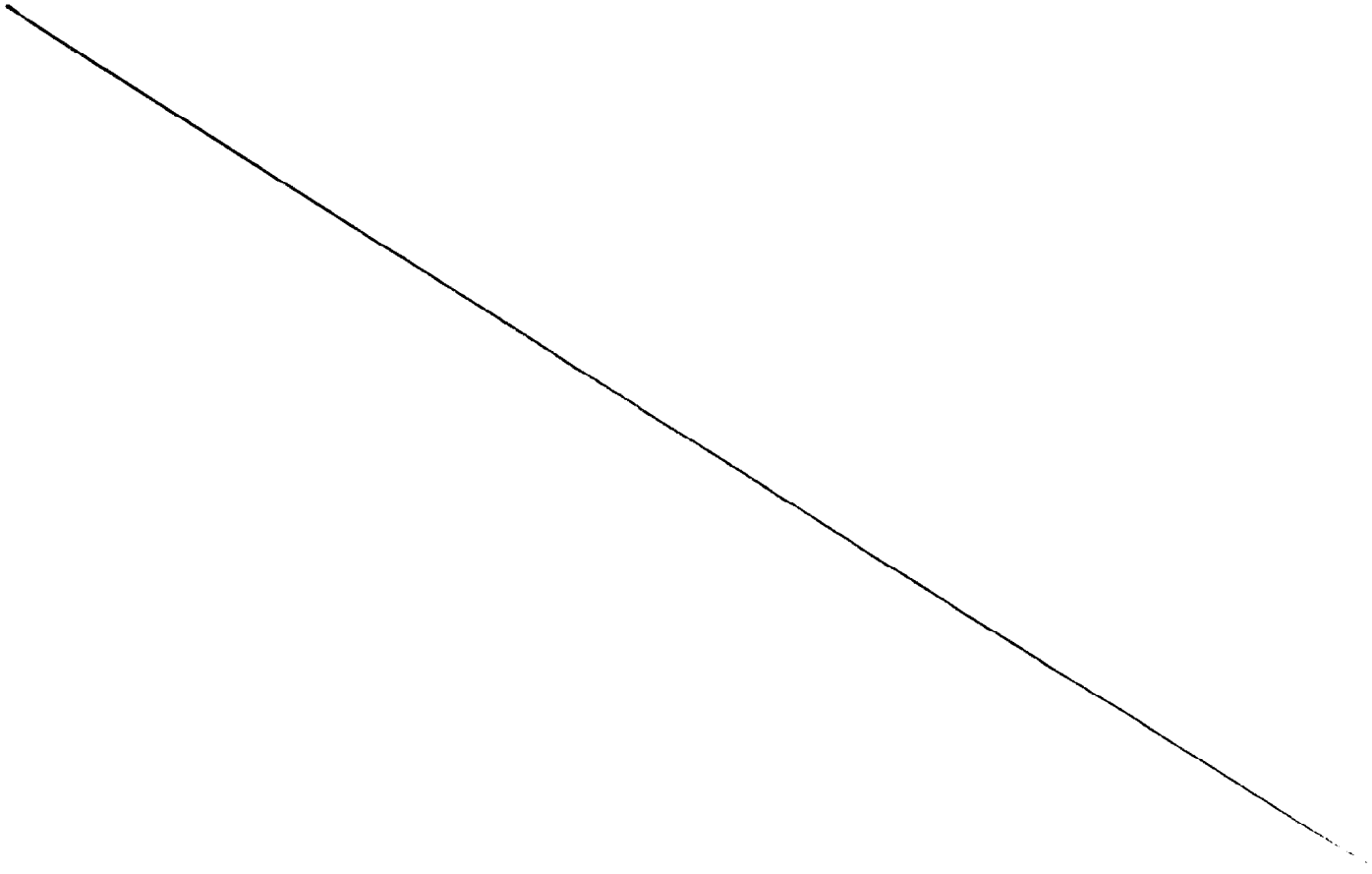
1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 866.5785 is added to subpart F to read as follows:

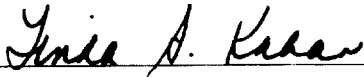
§ 866.5785 Anti-Saccharomyces cerevisiae (*S. cerevisiae*) antibody (ASCA) test systems.

(a) *Identification.* The Anti-Saccharomyces cerevisiae (*S. cerevisiae*) antibody (ASCA) test system is an in vitro diagnostic device that consists of the reagents used to measure, by immunochemical techniques, antibodies to *S. cerevisiae* (baker's or brewer's yeast) in human serum or plasma. Detection of *S. cerevisiae* antibodies may aid in the diagnosis of Crohn's disease.



(b) *Classification*. Class II (special controls). The special control is FDA's "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisiae* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications."

Dated: 11/9/00
November 9, 2000



Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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